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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,533	12/02/2005	Tadashi Okiyama	057788-0318680	9144

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PILLSBURY WINTHROP SHAW PITTMAN, LLP
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EXAMINER

PATEL, SHEFALI DILIP

ART UNIT	PAPER NUMBER
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3767

MAIL DATE	DELIVERY MODE
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06/11/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/559,533	Applicant(s) OKIYAMA, TADASHI	
	Examiner SHEFALI D. PATEL	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2005 and 21 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19, 21 and 22 is/are pending in the application.
- 4a) Of the above claim(s) 8-14 and 17-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 15, 16, 21 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 December 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>03/03/2006, 08/23/2007, 01/22/2008</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of species Group (a) (Figures 2-5), readable upon claims 1-7, 15, 16, 21, and 22, in the reply filed on April 21, 2008, is acknowledged.

Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file: JP 2003-194604 and JP 2004-183044.

Drawings

3. Figure 1 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claims 1 and 15 are rejected as failing to define the invention in the manner required by 35 U.S.C. 112, second paragraph.

The claim(s) are narrative in form and replete with indefinite and functional or operational language. The structure which goes to make up the device must be clearly and positively specified. The structure must be organized and correlated in such a manner as to present a complete operative device. The claim(s) must be in one sentence form only. Note the format of the claims in the patent(s) cited.

In regards to claims 1 and 15, the claims are indefinite since it is unclear what the applicant's invention is since the terms "comprising" or "consisting" have not been used to identify the elements of the "mixture injection port".

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

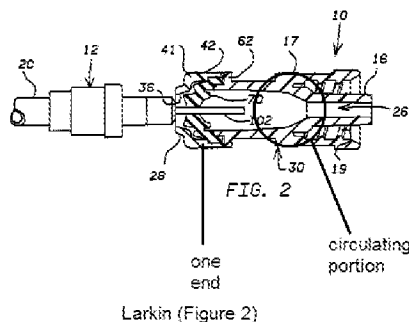
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 15, 16, 21, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Larkin (US 5,961,497).

In regards to claims 1, 15, and 16, Larkin teaches an injection port (Figures 1-3) in which one end (*labeled in Figure 2 below*) of a channel tube (connector [10]) is covered by a septum (seal [70]) provided with a slit (slit [74]) into which a tube member (cannula assembly [12]) is

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inserted, wherein the channel tube [10] is provided with a circulating portion/path (*labeled in Figure 2 below*).



In regards to claim 21 and 22, Larkin teaches a method for transferring a fluid to or from a body through a mixture injection port (Figures 1-3), the mixture injection port comprising a channel tube [10] with an end (*labeled in Figure 2 above*) that is covered by a septum [70] that is provided with a slit [74], the method comprising:

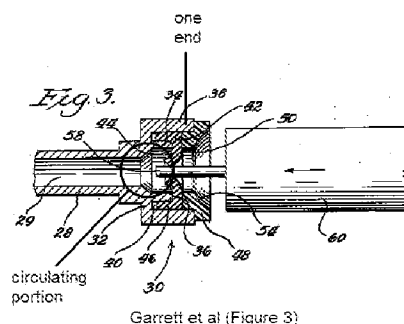
- a. inserting a tube member [12] into the slit [74] (Figure 1 to Figure 2) (column 7, lines 61-63)
- b. injecting the fluid into one of the tube member [12] and a downstream side of the channel tube [10], circulating the fluid to a side of the septum [70], and guiding the fluid to the other of the tube member [12] and the downstream side of the channel tube [10] (column 5, lines 8-20)(column 5, lines 30-35)

8. Claims 1, 15, 16, 21, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Garrett et al (US 4,197,848).

In regards to claims 1, 15, and 16, Garrett et al teaches an injection port (Figures 3-4) in which one end (*labeled in Figure 3 below*) of a channel tube (closed irrigation site [30]) is

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covered by a septum (membrane [42]) provided with a slit (slit [56]) into which a tube member (syringe [60]) is inserted, wherein the channel tube [30] is provided with a circulating portion/path (*labeled in Figure 3 below*).



In regards to claims 21 and 22, Garrett et al teaches a method for transferring a fluid to or from a body through a mixture injection port (Figures 3-4), the mixture injection port comprising a channel tube [30] with an end (*labeled in Figure 3 above*) that is covered by a septum [42] that is provided with a slit [56], the method comprising:

- a. inserting a tube member [60] into the slit [56] (Figure 3) (column 5, lines 1-5)
- b. injecting the fluid into one of the tube member [60] and a downstream side of the channel tube [30], circulating the fluid to a side of the septum [42], and guiding the fluid to the other of the tube member [60] and the downstream side of the channel tube [30] (column 5, lines 8-15)(column 5, lines 19-23)

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Larkin, as applied to claim 1 above, and further in view of Herlitze (US 4,601,703).

In regards to claim 2, Larkin teaches that the channel tube [10] comprises:

- a. a body portion (housing [24]) whose opening (opening [34]) is covered by the septum [70] and that is provided with an inner cavity (central passageway [26]) that is a space for accommodating the septum that is deformed by the insertion of the tube member [12] (Figure 2)
- b. a leg portion/narrow tube portion (tube [16]) in communication from the inner cavity to the other end of the channel tube (Figure 1)

Larkin does not teach that the circulating portion comprises a circulating-plate portion. Herlitze teaches a port having a channel tube (housing [16']) which comprises a circulating-plate portion (porous material [23]) mounted on a step (section [24]) between the inner cavity (section [21]) and the narrow tube portion (section [22]). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to incorporate the circulating-plate portion, as taught by Herlitze, onto the circulating portion of an injection port of Larkin, as the circulating-plate portion will enhance the flow of injected fluid through the port by filtering out solid particles that may contaminate the injected fluid that enters the body of the patient (column 1, lines 18-21).

11. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Garrett et al, as applied to claim 1 above, and further in view of Herlitze.

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In regards to claim 2, Garrett et al teaches that the channel tube [30] comprises:

- a. a body portion (base [32]) whose opening (mouth [44]) is covered by the septum [42] and that is provided with an inner cavity (irrigation path [29]) that is a space for accommodating the septum that is deformed by the insertion of the tube member [60] (Figure 3)
- b. a leg portion/narrow tube portion (tubular branch [28]) in communication from the inner cavity to the other end of the channel tube (Figure 3)

Garrett et al does not teach that the circulating portion comprises a circulating-plate portion.

Herlitzte teaches a port having a channel tube (housing [16']) which comprises a circulating-plate portion (porous material [23]) mounted on a step (section [24]) between the inner cavity (section [21]) and the narrow tube portion (section [22]). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to incorporate the circulating-plate portion, as taught by Herlitzte, onto the circulating portion of an injection port of Garrett et al, as the circulating-plate portion will enhance the flow of injected fluid through the port by filtering out solid particles that may contaminate the injected fluid that enters the body of the patient (column 1, lines 18-21).

12. Claims 2-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Larkin, as applied to claim 1 above, and further in view of Wiltse (US 3,880,401).

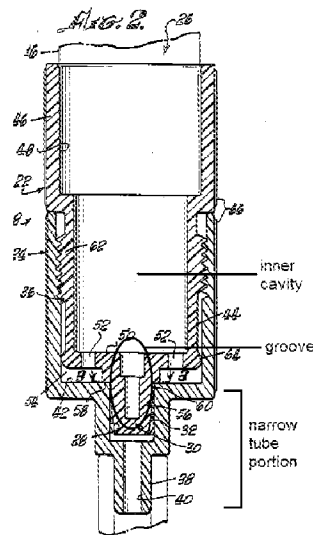
In regards to claims 2-5, Larkin teaches that the channel tube [10] comprises:

- a. a body portion (housing [24]) whose opening (opening [34]) is covered by the septum [70] and that is provided with an inner cavity (central passageway [26]) that is a

space for accommodating the septum that is deformed by the insertion of the tube member [12] (Figure 2)

- b. a leg portion/narrow tube portion (tube [16]) in communication from the inner cavity to the other end of the channel tube (Figure 1)

Larkin does not teach that the circulating portion comprises a circulating-plate portion. Wiltse teaches an injection port (Figure 2, valve [18]) having a channel tube (outer valve parts [22][24]) with a circulating-plate portion (flow metering valve plug [30]) mounted on a step (wall surface [42]) between the inner cavity (*labeled in Figure 2 below*) and the narrow tube portion (*labeled in Figure 2 below*). The circulating-plate portion also has a groove (*labeled in Figure 2 below*) on the surface of its inner cavity side, a holding portion (valve plug end [56]) engaged with the narrow tube portion, and a groove (flow slots [32]) on its back face. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to incorporate a circulating-plate portion, as taught by Wiltse, onto the circulating portion of an injection port of Larkin, as the circulating-plate portion will enable the user to regulate and block fluid flow through the injection port based on the fluid needs of the patient (column 2, lines 45-55).



Wiltse (Figure 2)

13. Claims 2-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garrett et al, as applied to claim 1 above, and further in view of Wiltse.

In regards to claims 2-5, Garrett et al teaches that the channel tube [30] comprises:

- a. a body portion (base [32]) whose opening (mouth [44]) is covered by the septum [42] and that is provided with an inner cavity (irrigation path [29]) that is a space for accommodating the septum that is deformed by the insertion of the tube member [60] (Figure 3)
- b. a leg portion/narrow tube portion (tubular branch [28]) in communication from the inner cavity to the other end of the channel tube (Figure 3)

Garrett et al does not teach that the circulating portion comprises a circulating-plate portion.

Wiltse teaches an injection port (Figure 2, valve [18]) having a channel tube (outer valve parts [22][24]) with a circulating-plate portion (flow metering valve plug [30]) mounted on a step (wall surface [42]) between the inner cavity (*labeled in Figure 2 above*) and the narrow tube

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portion (*labeled in Figure 2 above*). The circulating-plate portion also has a groove (*labeled in Figure 2 above*) on the surface of its inner cavity side, a holding portion (valve plug end [56]) engaged with the narrow tube portion, and a groove (flow slots [32]) on its back face. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to incorporate a circulating-plate portion, as taught by Wiltse, onto the circulating portion of an injection port of Garrett et al, as the circulating-plate portion will enable the user to regulate and block fluid flow through the injection port based on the fluid needs of the patient (column 2, lines 45-55).

14. Claims 2, 6, and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Larkin, as applied to claim 1 above, and further in view of Manske (US 4,141,379).

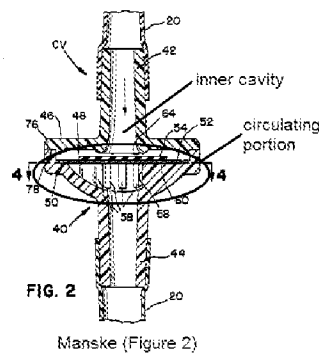
In regards to claim 2, Larkin teaches that the channel tube [10] comprises:

- a. a body portion (housing [24]) whose opening (opening [34]) is covered by the septum [70] and that is provided with an inner cavity (central passageway [26]) that is a space for accommodating the septum that is deformed by the insertion of the tube member [12] (Figure 2)
- b. a leg portion/narrow tube portion (tube [16]) in communication from the inner cavity to the other end of the channel tube (Figure 1)

Larkin does not teach that the circulating portion comprises a circulating-plate portion. Manske teaches a valve (Figure 2) with a circulating portion (*labeled in Figure 2 below*) which has a circulating-plate portion (screen [52]) that is mounted on a step (shoulder [50]) generated between the inner cavity (*labeled in Figure 2 below*) and the narrow tube portion (outlet [44]). It

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would have been obvious to a person having ordinary skill in the art at the time the invention was made to incorporate a circulating-plate portion, as taught by Manske, into the circulating portion of the injection port of Larkin, as the circulating-plate portion, being porous, will enhance the flow of injected fluid through the port (column 3, lines 45-52) by filtering out solid particles that may contaminate the injected fluid that enters the body of the patient.



In regards to claims 6 and 7, Larkin does not teach a protruding edge portion or a groove on the circulating portion. Manske teaches a circulating portion (*labeled in Figure 2 above*) with edge portions (Figure 4, ribs [58]) and grooves, situated between the ribs [58]. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the circulating portion of Larkin with edge portions and grooves, as taught by Manske, in a modified injection port of Larkin and Manske, as the structure of the edge portions and grooves of the circulating portion will function to guide fluid flow through the injection port and out into the patient's body through the outlet (column 3, line 68 to column 4, lines 1-2).

15. Claims 2, 6, and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garrett et al, as applied to claim 1 above, and further in view of Manske.

In regards to claims 2-5, Garrett et al teaches that the channel tube [30] comprises:

- a. a body portion (base [32]) whose opening (mouth [44]) is covered by the septum [42] and that is provided with an inner cavity (irrigation path [29]) that is a space for accommodating the septum that is deformed by the insertion of the tube member [60] (Figure 3)
- b. a leg portion/narrow tube portion (tubular branch [28]) in communication from the inner cavity to the other end of the channel tube (Figure 3)

Garrett et al does not teach that the circulating portion comprises a circulating-plate portion.

Manske teaches a valve (Figure 2) with a circulating portion (*labeled in Figure 2 above*) which has a circulating-plate portion (screen [52]) that is mounted on a step (shoulder [50]) generated between the inner cavity (*labeled in Figure 2 above*) and the narrow tube portion (outlet [44]). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to incorporate a circulating-plate portion, as taught by Manske, into the circulating portion of the injection port of Garrett et al, as the circulating-plate portion, being porous, will enhance the flow of injected fluid through the port (column 3, lines 45-52) by filtering out solid particles that may contaminate the injected fluid that enters the body of the patient.

In regards to claims 6 and 7, Garrett et al does not teach a protruding edge portion or a groove on the circulating portion. Manske teaches a circulating portion (*labeled in Figure 2 above*) with edge portions (Figure 4, ribs [58]) and grooves, situated between the ribs [58]. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the circulating portion of Garrett et al with edge portions and grooves, as taught by Manske, in a modified injection port of Garrett et al and Manske, as the structure of the edge portions and grooves of the circulating portion will function to guide fluid flow through the

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injection port and out into the patient's body through the outlet (column 3, line 68 to column 4, lines 1-2).

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Finley et al (US 6,595,964) and Arnett (US 5,817,069).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHEFALI D. PATEL whose telephone number is (571) 270-3645. The examiner can normally be reached on Monday through Thursday from 8am-5pm Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Shefali D Patel/
Examiner, Art Unit 3767
06/06/2008
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